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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Sterling et al.	Group Art Unit Unknown
Appl. No.	:	Unknown	
Filed	:	Herewith	
For	:	REAGENT-LESS WHOLE-BLOOD GLUCOSE METER	
Examiner	:	Unknown	

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on

January 21, 2002
(Date)

Mark J. Kertz, Reg. No. 43,771

PETITION TO MAKE SPECIAL FOR NEW APPLICATION UNDER 37 C.F.R. § 1.102 AND M.P.E.P. §708.02 [VIII]

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Under the provisions of 37 C.F.R. § 1.102 and M.P.E.P. §708.02 [VIII], Applicants hereby petition to make special the above-identified application in order to advance its examination in the Patent and Trademark Office. The application is being filed with this petition.

A check for the payment of the fee of $130 under 37 C.F.R. 1.17(h) is enclosed. Please charge any additional fees or credit overpayment to Deposit Account No. 11-1410.

Should a restriction requirement be necessary, Applicants request that prompt telephonic notice be given to Applicants' counsel, at which time Applicants will make an election without traverse.

A pre-examination search was conducted in the following areas:

Class 250, subclasses 339.1, 339.2

Class 356, subclasses 39-41

Class 422, subclass 82.05

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Applicants submit with this petition a copy of each reference not already of record deemed most closely related to the subject matter encompassed by the claims, including all references located during the search.

DISCUSSION OF THE REFERENCES

Applicants provide the following discussion of the references, which points out with the particularity required by 37 C.F.R. § 1.111(b) and (c) how the claimed subject matter is distinguished over the references.

U.S. Patent No. 3,787,124, to Lowy et al. ("Lowy")

The Lowy patent is directed to a dual wavelength photometer for absorbance difference measurements. The Lowy patent discloses chemistry-based measurement of oxygenation characteristics of blood wherein a chemical reaction is carried out in the titration cuvette 11. See, Column 3, lines 12-20. The apparatus generates spectra using the wavelengths 439 nm and 448 nm to determine oxygenation characteristics of blood. Column 3, lines 2-8.

U.S. Patent No. 3,972,614, to Johansen et al. ("Johansen")

The Johansen patent is directed to a method and apparatus for measuring one or more constituents of a blood sample. The Johansen patent discloses a hemoglobin measuring device 17 that is configured to hemolyze. Column 5, line 66 – column 6, line 12. The device 17 includes a fluid conduit system that carries blood through a measuring section 11, shown in FIG. 3. The measuring section 11 comprises a measuring chamber 34 defined between a pair of pane members 35 mounted in a frame 36. The frame 36 with the pane members 35 is arranged in a housing 30 between an inner end of a piston 25 and an annular backing member or anvil member 37. The end surface of the piston 25 contacting the adjacent pane member 35 has a recess receiving a photoelectric cell 40 which provides an electrical signal. Column 4, lines 7-27. A light source 41 from which light through a green light filter, which passes a wave length of about 505 nm, and a red light filter, which passes a wave length of about 600 nm. Column 4, lines 49-58. Vibrations are imparted to the measurement chamber via piezoelectric effect of a disk 27 (also indicated by the arrows in FIG. 3). Column 3, line 65 – column 4 line 3.

U.S. Patent No. 4,305,659, issued to Bilstad et al. ("Bilstad")

The Bilstad patent is directed to a photometric apparatus and method, and has a disclosure similar to that of Wicnienski. Bilstad discloses an apparatus that detects hemoglobin in plasma. Column 3, lines 8-10; column 3, lines 19-21.

U.S. Patent No. 4,350,441, issued to Wicnienski ("Wicnienski")

The Wicnienski patent is directed to a photometer apparatus and method. The Wicnienski apparatus, illustrated in Figure 1, is used to detect hemoglobin in plasma. Column 3, lines 8-10. The system comprises a light source 10 in the form of an LED having a peak wavelength of 565 nm (corresponding to the color green), and a light source 12 in the form of an LED having a peak wavelength of 635 nm (corresponding to the color red).

U.S. Patent No. 4,704,029, issued to Van Heuven ("Van Heuven")

The Van Heuven patent is directed to a blood glucose monitor. The Van Heuven patent discloses a monitor which measures the index of refraction of blood at an interface between a transparent material and the blood. Column 2, lines 42-51. In another embodiment, reflection is measured. See Figures 4 and 5 and accompanying text.

U.S. Patent No. 4,882,492, issued to Schlager ("Schlager")

The Schlager patent is primarily directed to noninvasive near infrared measurement of blood analyte concentrations. The Schlager patent discloses an in-vitro technique in connection with Figure 2. A halogen lamp 30, generates light which then passes through a diffuser 31 and is directed transmissively through a sample 32. Column 5, lines 32-35. Radiation from the source 30 is in a range from 900 nm to 1800 nm. Above 1800 nm, "transmissive measurements are impractical due to the high absorbance by water." Column 5, lines 43-48.

U.S. Patent No. 5,209,231, issued to Cote et al. ("Cote")

The Cote patent is directed to an optical glucose sensor apparatus and method. As shown in Figures 1-4, a polarized light is directed through an eye 32 of a patient. Glucose is measured to observing changes to the polarization vector of light when it interacts with the glucose. Column 5, line 35-39.

U.S. Patents Nos. 5,249,584, and 5,066,859 issued to Karkar et al. ("the Karkar patents")

The Karkar patents are directed to a hematocrit and oxygen saturation blood analyzer, and a syringe therefor. The Karkar patents disclose a blood analyzing device 10, shown in Figure 1, for measuring hematocrit and oxygen saturation. Column 2, lines 59-62. FIG. 5 shows a light emitting fiber 28 that transmits light at 805 nm into a syringe 8 from a first light emitting diode 42. The light emitting fiber 28 transmits light at 660 nm into the syringe 8 from a second light emitting diode 44. Column 8, lines 16-24. A first hematocrit detection fiber 34 detects scattered light from the first light emitting diode 42 to generate a first hematocrit voltage signal. Column 8, at lines 47-50. A second hematocrit detection fiber 36 detects scattered light from the first light emitting diode 42 to generate a second hematocrit voltage signal. Column 8, lines 50-53.

U.S. Patent No. 5,377,674, issued to Kuenstner ("the Kuenstner '674 patent")

The Kuenstner '674 patent is directed to a method for non-invasive and in-vitro hemoglobin concentration measurement. Column 3, lines 41-42. While Kuenstner does not disclose an apparatus in any great detail, in one example, a laboratory spectrophotometer, the NIRSystems Model 6500, is modified for an open cell and a vertical light path. Column 6, lines 46-47. The apparatus uses visible and near infrared wavelength radiation that are useful to determine hemoglobin content of the blood. Column 6 at lines 44-46.

U.S. Patent No. 5,567,869, issued to Hauch et al. ("Hauch")

The Hauch patent is directed to a method and apparatus for quantitation of relevant blood parameters. The Hauch patent discloses a method for estimating blood parameters in blood during the time period comprising shortly after sampling until about 30 minutes later. Column 1, lines 27-30. Such parameter are determined based on the shape of a translucence versus time curve. See, e.g., Column 2, lines 24-26; Column 4, lines 60-64. Figure 4 illustrates the translucence (the output, in milivolts, of a photodiode) versus time curve.

U.S. Patent No. 5,606,164, issued to Price et al. ("Price")

The Price patent is directed to a method and apparatus for biological fluid analyte concentration measurement using generalized distance outlier detection. Price is directed to handling sources of error in biological fluid analyte measurement, such as error related to sample preparation. Column 1, lines 63-65. Another source of error is caused by diluting saline solution

residue in a flowcell through which the sample is pumped. Column 2, lines 12-13. The Price patent discloses an apparatus 100 with a pump 102 into which a biological fluid sample is introduced and which circulates the sample through tubing 104 to fill flowcell 106.

U.S. Patent No. 5,857,462, issued to Thomas et al. ("the Thomas '462 patent")

The Thomas '462 patent is directed to a systematic wavelength selection for improved multivariate spectral analysis. The Thomas '462 patent is more particularly directed to minimizing cost and maximizing performance in a noninvasive medical instrument. Column 1, lines 19-30. The Thomas '462 patent purports to be an improvement on U.S. Patent No. 4,975,581, which the Thomas '462 patent asserts is directed to making noninvasive measurements. See Column 13, lines 34-36; Column 15, lines 34-36. Figure 9 is a schematic of a noninvasive finger sampling device. Figure 11 illustrates a noninvasive alcohol monitor incorporating the finger sampling device of Figure 9. Figures 12-14 illustrates other noninvasive monitoring embodiments.

U.S. Patent No. 5,963,335 Issued to Boutelle ("Boutelle")

The Boutelle patent is directed to a means and method for measuring absorption of radiation-scattering samples. Boutelle discloses an analyzer 10 which can take into account the scattering effects of particles in a sample. Column 4, lines 26-29. The analyzer includes an occluder 30, which is generally moveable from one position to another. Column 8, lines 32-34. As shown in Figure 7, this movement may be achieved by a motor 46. Column 8, lines 38-39; Column 16, lines 47-49. Figures 8-9 show a process requiring multiple measurement with different positions of the occluder 30.

U.S. Patent No. 5,971,941, issued to Simons et al. ("Simons")

The Simons patent is directed to an integrated system and method for sampling blood and analysis. Figure 7 shows a glucometer 166 that receives a cassette 150 in a recess 171. Column 12, lines 52-54. A sweeper 172 is used to sweep single cartridges to a position for use. Column 12, lines 54-56. The cassette 150 has a compartment for storing used test cartridges 158. Column 12, lines 19-21.

U.S. Patent No. 6,049,728, issued to Chou ("Chou")

The Chou patent is directed to a method and apparatus for noninvasive measurement of blood glucose by photoacoustics. Figure 1 and 2 shows the noninvasive photoacoustic measurement device. As can be seen, the photoacoustic system 10 is brought into contact with a body surface 24. Column 4, lines 39-48.

U.S. Patent No. 6,087,182, issued to Jeng et al.

The Jeng et al. patent is directed to determining concentration of an analyte in a biological sample, e.g., urine. Column 3, lines 38-42. Figure 2 shows a schematic drawing of an apparatus 100 having a spectral measurement assembly 102 and a fluid pump assembly 108. Column 14, lines 39-43. The spectral measurement assembly 102 includes a sample cell assembly 124. Column 14, lines 48-56.

A sample cell assembly 400 is shown in greater detail in Figures 7, 8, and 9A. The assembly 400 includes an inlet tube 406, an outlet tube 408, a spectroscopic measurement entrance window 410, and a spectroscopic measurement exit window 412. Column 16, lines 53-59. The spectroscopic windows 410, 412 are made of glass or fused silica. The refractive windows are made from glass, fused silica, or polymeric materials. Column 18, lines 10-13. Wavelengths disclosed as "suitable for spectroscopic measurement" range from 300 nm to 2500 nm. Column 18, lines 21-23.

U.S. Patent No. 6,157,041, issued to Thomas et al. ("the Thomas '041 patent")

The Thomas '041 patent is directed to a method and apparatus for tailoring spectroscopic calibration models. It is directed to improve a method and apparatus that noninvasively measures attributes of biological tissue. Column 5, lines 1-5. In practicing the method, "an analyte containing tissue area is selected as the point of analysis [which] area can include the skin surface on the finger, earlobe, forearm, or any other skin surface." Column 5, lines 55-59. The Thomas '041 patent notes that "it is difficult to find a part of the body which is optically thin enough to pass near infrared light through, especially at longer wavelengths. Thus, the preferred method for measurement in the present invention is to focus on the reflectance of light from the sample." Column 11, lines 62-66. The Thomas '041 patent utilizes infrared radiation in a range between 1.0 and 2.5 um. Column 12, lines 29-30.

U.S. Patent No. 6,236,047 B1, Issued to Malin et al. ("Malin")

The Malin patent is directed to a method for multi-spectral analysis of organic blood analytes in using infrared spectroscopy. An apparatus 10 that determines the concentration of an analyte in a liquid sample medium 16. Column 9, lines 22-25. The apparatus 10 includes a radiation source 12 that provides a plurality of wavelengths between 1100 to 5000 nm. Column 9, lines 26-28. The source 12 directs radiation through an optic interface 14 toward the liquid sample medium 16. After contacting the liquid sample medium 16, radiation emerging from the liquid sample medium 16 "as diffusively reflected light" is collected and analyzed. Col. 9, lines 43 – 46.

U.S. Patent No. 6,236,870, Madarasz et al. ("Madarasz")

The Madarasz patent is directed to a photonic molecular probe, which, as shown in Figures 4 and 5, is a noninvasive device. As shown, the apparatus receives a finger which is inserted into the finger cell 30. In one embodiment, the finger cell 30 can be a sample cell "adapted for receiving a particular mixed specimen." Column 11 lines 18-20. Mixed specimens "may be placed in a suitably adapted specimen cell for analysis." Column 11, lines 26-28. The photonic molecular probe employs opto-electronic processes corresponding to scattering, including absorption and transmission. In order to establish a reference, "the beam, before entering the sample, must be unambiguously optically configured." Column 4, lines 13-15. Column 3, lines 2-5; Column 3, lines 8-10. In the "most basic method . . . all the wavelength components of the polychromatic light will be polarized." Column 4, lines 8-12.

U.S. Patent No. 6,262,798, issued to Shepherd et al. (Shepherd)

The Shepherd patent is directed to a method and apparatus for direct spectrophotometric measurements in unaltered whole blood. The Shepherd patents discloses using transmittance to assess concentration of hemoglobin (and the concentrations of hemoglobin's various forms) in blood. The apparatus is shown in FIG. 6, and includes a computer-controlled light source 10 capable of emitting radiation at at least 7 different "substantially monochromatic wavelengths." Column 8, lines 26-29. The wavelengths used to analyze the whole-blood are between 488.4 and 630 nm. Column 10, lines 62-65; column 14, lines 16-19. The apparatus also includes an "ultrathin" optical cuvette 11, a large-area light detector 12, and control circuitry 14. The cuvette is made thin to reduce the degree of scattering (by reducing the number of scattering

interactions). The optical pathlength is between 80 and 150 um. In one embodiment, the OPL is 90 +/- 10 um.

U.S. Patent No. 6,278,889, issued to Robinson ("Robinson")

The Robinson patent is directed to a robust accurate non-invasive analyte monitor. As is shown in Figure 32 – 37, the monitoring is done through a finger.

U.S. Patent No. 6,285,448, issued to Kuenstner ("the Kuenstner '448 patent")

The Kuenstner '448 patent is directed to clinical analyte determination by infrared spectroscopy, including noninvasive and minimally invasive measurements. Column 5, lines 23-24. The minimally invasive method involves contacting a sample of interstitial fluid on a pane of an optically clear window, placing a second window against the sample to create "a sandwich of liquid film between the windows." Column 5, lines 25-30. The method is considered "minimally invasive" because it employs a SpectRx device, which has a laser that creates a "tiny, shallow ulcer, or micropore, on a patients skin." Column 5, lines 52-55. No sample cell is provided because in the sandwich, "[s]trict control over the thickness of the sample 10 (pathlength) is not required." Column 7, lines 4-5. The Kuenstner '448 patent does disclose controlled pathlength application, but this is done for serum. Column 8, lines 55-56.

PCT Publication WO 01/53806A1

PCT Publication WO 01/53806A1 is directed to providing a method and apparatus which provide correction for the influence of scattering. Page 7, lines 23-26. The disclosed embodiment has a sample cuvette 15 that has a sample inlet 17a, an outlet 17b and a liquid sensor 17c. Page 19, lines 33-34.

CONCLUSION

In view of the foregoing discussion, Applicants respectfully submit that the present invention is patentable over all of the references discussed above. More specifically, the reference do not anticipate or render obvious the systems or methods of the present invention comprising, in one form thereof, a reagentless whole-blood analyte detection system capable of being deployed near a patient comprising: a source capable of emitting a beam of radiation comprising a spectral band having a center wavelength; a detector in an optical path of the beam;

a housing configured to house the source and the detector; and a sample element situated in the optical path of the beam and configured to be filled with a sample, the sample element comprising: a sample cell wall that does not eliminate transmittance of the radiation in the spectral band; and a sample cell.

Accordingly, the Applicants respectfully request expedited allowance of the claims.

Applicants further respectfully submit that the requirements set forth under M.P.E.P. § 708.02 [VIII] for accelerated examination of the above-identified application have been satisfied. Therefore, Applicants respectfully request that this petition be granted.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1/21/02

By: _____

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